DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#4

Re: Zerit®
Docket No. 94E-0332

NOV -7 1994

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,978,655, filed by Yale Univeristy, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Zerit®, the human drug product claimed by the patent.

The total length of the regulatory review period for Zerit® is 1,984 days. Of this time, 1,805 days occurred during the testing phase and 179 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 19, 1989.

   The applicant claims March 1, 1989, as the date the Investigational New Drug application (IND) for Zerit® (IND 32,486) became effective. However, FDA records indicate that the IND 32,486 was received by the agency on December 16, 1988. It was placed on clinical hold January 3, 1989 and was removed from hold on January 19, 1989. Therefore, the IND effective date is January 19, 1989 (the date IND 32,486 was removed from hold).

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: December 28, 1993.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for Zerit® (NDA 20-412) was initially submitted on December 28, 1993.

3. The date the application was approved: June 24, 1994.

   FDA has verified the applicant's claim that NDA 20-412 was approved on June 24, 1994.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Dominic M. Mezzapelle
Associate General Counsel-Patents
Bristol-Myers Squibb Company
345 Park Avenue
New York, NY 10154